

Dkt. 50634-B/JPW/JML/YL

## STATES PATENT AND TRADEMARK OFFICE

Applicants

Eric Rose, et al.

Serial No.

09/053,872

Filed

April 1, 1998

Art Unit: 1643

For

METHODS FOR INHIBITING THROMBOSIS IN A RECTIVED PATIENT WHOSE BLOOD IS SUBJECTED TO EXTRACORPOREAL CIRCULATION

**GROUP 1800** 

1185 Ave. of the Americas New York, New York 10036 November 24, 1998

Assistant Commissioner for Patents Washington, D.C. 20231

Sir:

## INFORMATION DISCLOSURE STATEMENT

In accordance with their duty of disclosure under 37 C.F.R. \$1.56, applicants would like to direct the Examiner's attention to the following documents, which are listed on Form PTO-1449 and are also listed below. Copies of the documents were previously submitted in connection with copending, coassigned, U.S. Serial No. 08/648,561, filed May 16, 1996, of which the above identified patent application is a continuation-in-part. The documents listed herebelow as items 1-14 are again listed on Form PTO-1449 which is attached hereto as Exhibit 1.

- 1. Bazan, J. F., Big rigs in blood coagulation, Nature 380:21-23, 03/1996;
- Benedict, C.R. et al., Active site-blocked factor IXa 2. prevents intravascular thrombus formation in the coronary vasculature without inhibiting extravascular coagulation in a canine thrombosis model, <u>J. Clin. Invest.</u>, 88:1760-1765, 1991;

DEC 0.4

Eric Rose, et al. U.S. Serial No.: 09/053,872 Filed: April 1, 1998

Page 2

- 3. Benedict, C. R., et al., Endothelial-Dependent Procoagulant and Anticoagulant Mechanisms, <u>Texas Heart Institute Journal</u>, 21: 86-90, 1994;
- 4. Berntorp, E., Biochemical and in vivo properties of high purity factor IX concentrates, <u>Thrombosis and Haemostasis</u> 70(5):768-773, 11/1993;
- 5. Freedman, S.J. et al., Structure of the metal-free γ-carboxyglutamic acid-rich membrane binding region of factor IX by two-dimensional NMR spectroscopy, <u>J. Biol. Chem.</u>, 270(14):7980-7987, 04/1995;
- 6. Furie, B.C. and Furie, B. (1995) Biosynthesis of factor IX: implications for gene therapy, <u>Thrombosis and Haemostasis</u>, 74(1):274-277;
- Iberti, T.J. et al., Abnormal coagulation profile in brain tumor patients during surgery, <u>Neurosurgery</u>, 34(3):389-395, 03/1994;
- 8. Kirchhofer, et al. (1995) Active site-blocked factors VIIa and IXa differentially inhibit fibrin formation in a human ex vivo thrombosis model, <u>Arterioscler. Thromb. Vasc. Biol.</u>, 15:1098-1106:
- 9. Kuwabara, K. et al., Calreticulin, an antithrombotic agent which binds to vitamin K-dependent coagulation factors, stimulates endothelial nitric oxide production, and limits thrombosis in canine coronary arteries, <u>J. Biol. Chem.</u>, 270(14):8179-8187, 04/1995;

DEC 0.4 FMB GROUP 180°

Eric Rose, et al. U.S. Serial No.: 09/053,872 Filed: April 1, 1998

Page 3

- 10. Miyata, T. et al., Factor IX Bm Kiryu: a Val-313-to-Asp substitution in the catalytic domain results in loss of function due to a conformational change of the surface loop: evidence obtained by chimeric modeling, <a href="https://doi.org/10.1001/journal.com/Brit.J.Of/Haematol.">Brit. J. Of/Haematol.</a>, 88(1):156-165, 09/1994;
- 11. Santagostino, E. et al., Markers of hypercoagulability in patients with hemophilia B given repeated, large doses of factor IX concentrates during and after surgery, <u>Thrombosis and Haemostasis</u>, 71(6):737-40, 06/1994;
- 12. Wacey, A.I. et al., Determinants of the factor IX mutational spectrum in hemophilia B: an analysis of missense mutations using a multi-domain molecular model of the activated protein, <a href="https://doi.org/10.1001/j.model.com/"><u>Hum. Genet.</u></a>, 94(6):594-608, 12/1994;
- 13. Warrier, I. et al., Safety of high doses of a monoclonal antibody-purified factor IX concentrate, <u>Am. J. Of</u> Hematol., 49(1):92-94, 05/1995;
- 14. Wong, A. G. et al., Relative efficacy of active siteblocked factors IXa Xa in a model of venous thrombosis, <u>Supplement I Circulation</u>, Abstract # 3293 p. I-686, Vol. 92 No. 8, 10/1995;

Applicants request that the Examiner review the references and make them of record in the subject application.

Eric Rose, et al. U.S. Serial No.: 09/053,872 Filed: April 1, 1998

Page 4

No fee is deemed necessary in connection with the filing of this Information Disclosure Statement. If any such fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents Washington, D.C.

White No. 28,678

20231.

White John Þ.

Registration No. 28,678 Attorney for Applicants Cooper & Dunham LLP 1185 Avenue of the Americas

New York, New York 10036

(212) 278-0400



## RECFIVED OEC 0 4 1998

GROUP 1800 Sheet 1 of 3

Form PTO-1449 (Substituted) (REV. 8-83)

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO. 50634-B/JPW/JML/YL SERIAL NO. 09/053,872

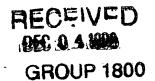
APPLICANTS.

INFORMATION DISCLOSURE CITATION								APPLICANTS Eric Rose, et al.								
		J	171	OR					inecessary)	FILING DATE April 1, 1998	GROUP <del>1843</del> んろろ					
								U.S	S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER						DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE				
	_															
			$\perp$													
				Ì		1										
	T			$\neg \vdash$		Γ										
	$\dashv$	-†	十	_	<del>                                     </del>	$\top$	1									
	+	$\dashv$	+	+	╁	╁╌	+									
			4	- -	+	┼	+				-					
			$\perp$			↓_	ļ									
						L										
	1	$\neg \uparrow$	十	_		$\top$										
	十		$\dashv$		1	+	+									
		1	L		i	Щ.		FORE	LIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER				ARE!	R	DATE COUNTRY CI			SUBCLASS	TRANS	LATION			
		DOCOMENT NOMBER						57.1.2				Yes No				
			$\neg$			T							<u> </u>			
	_		7	_	_	$\top$	1									
<del></del>	$\dashv$		-		-	+	+-	<del> </del>				<u> </u>				
<b></b>	_		4			+	+	<del> </del>				<del>                                     </del>	<u> </u>			
	1						丄					<u> </u>				
									${f S}$ (Including Author, Title, Date, Pe		<u>c.)</u>					
Can		Bazan, J. F., Big rigs in blood coagulation, Nature,														
		380:21-23, 03/1996;														
		Ben	ed.	ict	, c	.R	ξ. (	et al.,	Active site-blocked	Eactor IXa	preven	ts				
M		intravascular thrombus formation in the coronary vasculature without inhibiting extravascular coagulation in a canine thrombosis model,														
11/4									ar coaguración in a co							
1	Ī	J. Clin. Invest., 88:1760-1765, 1991;														
EXAMINE		Sef		e, E				DATE CON	sidered November 3, 2001							
*EXAMINER	e: In	itial	; <i>f</i>	cita	tion	con	ns i de	red, whethe	er or not citation is in conformance	with MPEP 609: Dra	aw line th	rough cit	tation			
if not in	con	forma	nce	and	not (	cons	ider	ed. Include	copy of this form with next communi	cation to applicar	π.					

Eric Rose, et al. U.S. Serial No.: 09/053,872 Filed: April 1, 1998 Exhibit 1



الماري



Sheet 2 of 3

ATTY. DOCKET NO. 50634-B/JPW/JML/YL SERIAL NO. Form PTO-1449 (Substituted) U.S. DEPARTMENT OF COMMERCE 09/053,872 (REV. 8-83) PATENT AND TRADEMARK OFFICE APPLICANTS Eric Rose, et al. INFORMATION DISCLOSURE CITATION FILING DATE GROUP (Use several sheets if necessary) 1643 1653 April 1, 1998 OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) Benedict, C. R., et al., Endothelial-Dependent Procoagulant and Anticoagulant Mechanisms, Texas Heart Institute Journal, 21: 86-90, 1994; Berntorp, E., Biochemical and in vivo properties of high purity factor IX concentrates, Thrombosis and Haemostasis, 70(5):768-773, 11/1993; Freedman, S.J. et al., Structure of the metal-free y-carboxyglutamic acid-rich membrane binding region of factor IX by two-dimensional NMR spectroscopy, <u>J. Biol. Chem.</u>, 270(14):7980-7987, 04/1995; Furie, B.C. and Furie, B. (1995) Biosynthesis of factor IX: implications for gene therapy, Thrombosis and Haemostasis, 74(1):274-277; Iberti, T.J. et al., Abnormal coagulation profile in brain tumor patients during surgery, Neurosurgery, 34(3):389-395, 03/1994; Kirchhofer, et al. (1995) Active site-blocked factors VIIa and IXa differentially inhibit fibrin formation in a human ex vivo thrombosis model, <u>Arterioscler. Thromb. Vasc. Biol.</u>, 15:1098-1106; Kuwabara, K. et al., Calreticulin, an antithrombotic agent which binds to vitamin K-dependent coaqulation factors, stimulates endothelial nitric oxide production, and limits thrombosis in canine coronary arteries, J. Biol. Chem., 270(14):8179-8187, 04/1995; Miyata, T. et al., Factor IX Bm Kiryu: a Val-313-to-Asp substitution in the catalytic domain results in loss of function due to a conformational change of the surface loop: evidence obtained by chimeric modeling, Brit. J. Of Haematol., 88(1):156-165, 09/1994; DATE CONSIDERED November 3, 2001

\*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation

if not in conformance and not considered. Include copy of this form with next communication to applicant.



## RECFIVED SEC 0 4 1999

**GROUP 1800** 

Sheet 3 of 3 U.S. DEPARTMENT OF COMMERCE ATTY. DOCKET NO. 50634-B/JPW/JML/YL

APPLICANTS Eric Rose, et al

SERIAL NO. 09/053,872

Form PTO-1449 (Substituted)

(REV. 8-83)

INTURIVIA	Life Nose, et al.										
l .	Use several sheets if necessary)		FILING DATE April 1, 1998	GROUP 1 <del>643</del> (653							
OTHER	R DOCUMENTS (Including Author, Tit	le, Date, Pertinent	Pages, Etc.)								
with hemophi	Santagostino, E. et al., Markers of hypercoagulability in patients with hemophilia B given repeated, large doses of factor IX concentrates during and after surgery, Thrombosis and Haemostasis,										
71(6):737-40	, 06/1994;										
in hemophili	Wacey, A.I. et al., Determinants of the factor IX mutational spectrum in hemophilia B: an analysis of missense mutations using a multidomain molecular model of the activated protein, Hum. Genet.,										
94(6):594-60	94(6):594-608, 12/1994;										
Warrier, I. purified fac	Warrier, I. et al., Safety of high doses of a monoclonal antibody- purified factor IX concentrate, <u>Am. J. Of Hematol.</u> ,										
49(1):92-94,	05/1995;										
Wong, A. G. IXa Xa in a	et al., Relative efficad model of venous thrombos	cy of active sis, <u>Supple</u>	site-block ment I Circ	ed factors <u>ulation</u> ,							
Abstract # 3	Abstract # 3293 p. I-686, Vol. 92 No. 8, 10/1995;										
EXAMINER STEEL EN	DATE CONSIDERED Nave	Lr 3 2001									

\*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.